

BACKGROUND OF THE INVENTION--.

IN THE CLAIMS:

Please cancel claims 13 and 14, without prejudice, and amend the following claim.

12. (Amended) The nucleic acid of claim 11, wherein said nucleic acid is labeled with a label selected from the group [consisiting] consisting of a radioisotope, an enzyme, a [fluorscent] fluorescent label, and a chromophore label.

REMARKS

Applicants respectfully request reconsideration and reexamination of this application.

The specification has been amended to recite the correct file history of this application, as requested by the Examiner. In addition, claims 13 and 14 have been cancelled, without prejudice, and claim 12 has been amended. Claims 13 and 14 were cancelled in response to the Examiner's Restriction Requirement. Applicants reserve the right to prosecute the subject matter of these claims in a later application. Claim 12 was amended to correct two misspelled words, as requested by the Examiner. As the foregoing amendments do not introduce any new matter, it is respectfully requested that they be entered by the Examiner.

The Examiner noted that the Preliminary Amendment filed January 5, 1993 contained duplicative and contradictory information regarding the file history of this application. Applicants have amended the specification to recite the correct file history.

Claims 11 and 12 were rejected under 35 U.S.C. § 101 because the invention as claimed allegedly lacks patentable utility and as disclosed is inoperative. Applicants respectfully traverse this ground for rejection.

As noted by the Examiner, applicants teach that the "invention also relates more specifically to cloned probes which can be made starting from any DNA fragment according to this invention . . ." See page 4 of Paper No. 7; and page 14, lines 11-19 of the specification. Such probes are useful in hybridization assays to detect the presence or absence of HIV. See page 14, lines 17-32 of the specification.

In disagreeing with this utility, the Examiner stated that

applicant has not demonstrated a utility for the HIV LTR sequences as a probe. How specific is the LTR for detecting HIV? Is there cross-hybridization with other retroviral LTRs, in particular to the HTLV types I and II?

See page 5 of Paper No. 7. Applicants respectfully disagree with the Examiner.

All that is required to demonstrate enablement for an invention is some utility. See M.P.E.P. § 608.01(p); and E.I. duPont de Nemours & Co. v. Berkley & Co., 205 U.S.P.Q. 1, 10 n.17 (8th Cir. 1980) ("a small degree of utility is sufficient. The claimed invention must only be capable of performing *some* beneficial function. An invention does not lack utility merely because the particular embodiment disclosed in the patent lacks perfection or performs crudely. . . . Nor is it essential that the invention accomplish all its intended functions . . . partial success being sufficient to demonstrate patentable

utility . . .") (emphasis in original, citations omitted) (Exhibit 1). See also Envirotech Corp. v. Al George, Inc., 221 U.S.P.Q. 473, 480 (Fed. Cir. 1984) ("the defense of non-utility cannot be sustained without proof of total incapacity.") (Exhibit 2).

The claimed nucleic acid satisfies the "some" utility requirement as it is useful in hybridization assays to detect the presence or absence of HIV. Accordingly, the withdrawal of this ground for rejection is respectfully requested.

Claim 12 was rejected under 35 U.S.C. § 112, first paragraph, "as the disclosure is enabling only for claims limited to the nucleic acid having the sequence of claim 11." See pages 5-6 of Paper No. 7. Applicants respectfully traverse this ground for rejection.

Labeling of nucleic acids is disclosed in the specification at, for example, page 14, lines 11-19 and 25-29. Moreover, it is courteously submitted that labeling of nucleic acids was well known in the art at the time the claimed invention was made. For example, the use of radioactively labeled nucleic acid probes is described by Adams, "Cell Culture for Biochemists," Work et al. eds., Laboratory Techniques in Biochemistry and Molecular Biology, pages 181-201 (Elsevier/North-Holland Biomedical Press, New York, NY 1980) (Exhibit 3); and Maniatis et al., Molecular Cloning, pages 324-328 and 470-473 (Cold Spring Harbor Laboratory, 1982) (Exhibit 4). The use of fluorescent (enzyme) labeled DNA is described at pages 282-283 and 468-469 of Maniatis et al.

As applicants describe labeling of nucleic acid in the specification, and as techniques for labeling DNA were well known in the art at the time the claimed invention was made, applicants' claimed invention is enabled. See M.P.E.P. 608.01(p); and In re Strahilevitz, 212 U.S.P.Q. 561, 564 (C.C.P.A. 1982) ("[Appellant] properly relies on literature citations to establish both the level of ordinary skill in the art and the fact that the techniques necessary to practice his invention were known in the art.") (Exhibit 5). Accordingly, the withdrawal of this ground for rejection is respectfully requested.

It is courteously submitted that this application is now in condition for allowance. Reconsideration and reexamination of this application, and allowance of the pending claims at the Examiner's convenience, are respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this Amendment to our Deposit Account No. 06-0916.

Respectfully submitted,

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